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| FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110 | | | ART UNIT 1651 | PAPER NUMBER |

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,360

Applicant(s)

BONASSAR ET AL.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

An amendment of 12/23/04 amended the specification and claims 1, 4, 13, 16 and 17, canceled claim 15, and added new claim 19.

Claims examined on the merits are 1-14 and 16-19, which are all
5 claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as
10 being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 2 of the claim, "and other cells that form cartilage" is uncertain as to cells that form and do not form cartilage.

Applicants assert that the phrase has been deleted. However,
15 while claim 18 is indicated as "currently amended", no change is found in the claim. The phrase has not been lined through to show that it is canceled.

Claim Rejections - 35 USC § 103

Claims 1-12, 14 and 16-19 are rejected under 35 U.S.C. 103(a) as
20 being unpatentable over Scholz (5,141,747) in view of Purchio et al (5,919,702) and Vacanti et al (6,171,610 B1) taken with Neefe (4,659,524), and if necessary in further view of Samuelsin (6,051,249) for reasons in the previous office action of 9/20/04, and for reasons herein.

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The claims are drawn to making a construct for repairing a perforation in a tympanic membrane. The method contains steps of providing a negative mold having a negative shape of the construct, suspending isolated tissue precursor cells in a hydrogel to form a liquid hydrogel-precursor cell composition, introducing the composition into the mold, causing the composition to gel in the mold to form the construct, and removing the construct from the mold to provide a tissue construct having a shape suitable for insertion into a perforation in a tympanic membrane. Also claimed is using the construct to repair a perforation in a tympanic membrane.

Scholz discloses (col 2, lines 27-39) producing a collagen membrane by casting heated collagen molecules into a desired shape, such as a film, and then allowing the collagen to cool and gel. The gel is cross-linked to form the membrane. Cross-linking can result from dehydrating the gel (col 2, lines 38-39). The membrane can be used in tympanic membrane repair (col 2, lines 33-36 and col 5, lines 29-68).

Purchio et al discloses forming cartilage tissue for replacement of damaged cartilage tissue, which contains collagen (col 1, lines 36 and 44). Isolated chondrocytes are suspended in a hydrogel solution, such as prepared from polyphosphazenes, polyacrylates or alginate which can be cross-linked with a divalent metal ion, (col 15, lines 1-45). The cell-containing hydrogel solution can be added to a mold and then hardened (col 14, lines 63-65) to form a matrix, which can be implanted to form new cartilage tissue. For creating tissue *in vitro*,

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cells are added to a matrix and then cultured *in vitro* to form the tissue (paragraph bridging cols 19 and 20).

Vacanti et al disclose forming tissue to replace damaged tissue by delivering a liquid hydrogel-cell composition, which contains a hydrogel and tissue precursor cells, into a support structure. As the composition solidifies, it takes the shape of the support structure, and new tissue is formed as the cells grow and multiply (col 1, lines 40-67, col 2, lines 21-65 and col 9, lines 5-22). The support structure can be polymer fibers, which can be compressed in a mold to form the desired shape (col 7, lines 44-50).

Neefe discloses making contact lenses using a negative mold. Heated soft resinous material is added to a convex negative mold having the shape of the lens such that the material assumes the shape of the mold, and allowing the material to cool and form a solid concave image of the mold (col 4, lines 12-35).

Samuelsen discloses using negative molding to produce a dressing by compression of a sheet of laminate between a positive and negative mold (col 9, lines 25-27 and 41-42).

It would have been obvious to substitute for the collagen membrane used by Scholz for tympanic membrane repair, tympanic membrane tissue produced by adding cells to a hydrogel solution followed by adding the solution to a mold of a desired shape, and gelling the hydrogel and culturing the cells as suggested by Purchio et al and Vacanti et al since the tissue produced in this manner would have been expected to provide the function of the collagen membrane

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and be superior to the collagen membrane by being more similar to tympanic membrane tissue. Using a negative mold to provide a desired shape would have been obvious when the shape desired is that formed by a negative mold as suggested by Neefe, and if needed as further suggested by Samuelsen. The conditions of dependent claims would have been matters of obvious choice in view of the disclosures of the references. The percentages of claims 6-8, concentration of claim 11 and time of claim 13 are a matter of obtaining individual preferred conditions using limited routine experimentation, and would have been within the skill of the art. As to claim 19, injecting the cell-containing solution into the mold, this would have been an obvious way of introducing the solution into the mold.

Claim Rejections - 35 USC § 103

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-12, 14 and 16-19 above, and further in view of Abbott et al for reason in the previous office action.

The claim requires preparing the negative mold using CAD/CAM or rapid prototyping.

Abbott et al discloses using computer-aided design or computer-aided manufacturing to producing a nylon model of traumatized mandible.

When using a negative mold as set forth above to produce tympanic membrane tissue, it would have been obvious to use a computer in construction of the mold as suggested by Abbott et al. Furthermore,

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the present specification discloses that computer hardware and software are available and can be employed using known techniques in the art (page 6, lines 23-25).

Response to Arguments

5 Applicant's arguments filed 12/23/04 have been fully considered but they are not persuasive.

Applicants urge that Scholz does not disclose or suggest the use of living tissue. However, obviousness is not based on Scholz alone but on Scholz in combination with the Purchio et al and Vacanti et al
10 references which clearly suggest living tissue to repair tissue in the body that has been damaged.

While Purchio et al and Vacanti et al may not disclose repairing a perforation in a tympanic membrane, making such a repair is suggested by Scholz, and by Vacanti et al disclosing preparing tissue
15 using tympanic membrane cells (col 12, line 57). The references are applied in combination, and must be considered together as a whole, and not each alone. The living tissue produced by Purchio et al and Vacanti et al can be used for repair in various parts of the body depending on the tissue desired to be repaired. Repairing a
20 perforation in a tympanic membrane with living tissue would have been expected to be advantageous for the same reason that Purchio et al and Vacanti et al prepare and use living tissue for tissue repair. A tympanic membrane is tissue, and to make tissue for repair of this tissue by the procedure suggested by Purchio et al and Vacanti et al
25 would have been obvious for the same reason that Purchio et al and

5 It is granted as urged by applicants that the procedure used by
Scholz for preparing a collagen membrane may be incompatible with
living cells. However, obviousness is not based on using living cells
in the procedure of Scholz, but on producing living tissue by the
procedure suggested by Purchio et al and Vacanti et al, and using a
10 negative mold as suggested by Neefe, and if needed Samuelsin, to
produce living tissue for repair of a perforated tympanic membrane,
which Scholz suggest repairing. It is clear from Vacanti et al that
the living tissue can be produced in any shape desired, and it would
have been expected that living tissue can be produced as suggested by
15 Purchio et al and Vacanti et al in a shape suitable for repairing a
perforation in a tympanic membrane. As noted above, Vacanti et al
suggest using tympanic membrane cells to prepare tissue, and tissue
prepared using these cells is intended for repair of a tympanic
membrane.

20 *Conclusion*

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date

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of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be
5 calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff
10 whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this
15 application or proceeding is assigned is 703-872-9306.

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5 from either Private PAIR or Public PAIR. Status information for
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more information about the PAIR system, see [http://pair-](http://pair-direct.uspto.gov)
[direct.uspto.gov](http://pair-direct.uspto.gov). Should you have questions on access to the Private
PAIR system, contact the Electronic Business Center (EBC) at 866-217-
10 9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN
3/24/05